

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

**Amendment**

**In the Claims**

1. (Currently Amended) A topical foam aerosol formulation comprising
  - (a) an active agent or agents selected from the group consisting of anti-inflammatory agents, topical anesthetics, topical antibiotics, anti-fungal agents, and combinations thereof, solubilized or dispersed in an oil and water emulsion, wherein the emulsion does not contain volatile lower alcohols and wherein the oil phase of the emulsion is a solid or semi-solid at room temperature; and
  - (b) a propellant consisting essentially of a hydrofluoroalkane or a mixture of hydrofluoroalkanes, without additional co-solvents or co-propellants, contacting the emulsion to produce an immediate foaming action on expulsion from a pressurized container.
2. (Canceled)
3. (Previously Presented) The formulation of claim 1 wherein the active agent is an anti-inflammatory agent.
4. (original) The formulation of claim 3 wherein the anti-inflammatory agent is selected from the group consisting of alclometasone dipropionate, amcinonide, beclamethasone dipropionate, betamethasone benzoate, betamethasone dipropionate, betamethasone valerate, budesonide, clobetasol propionate, clobetasone butyrate, desonide, desoxymethasone, diflorasone diacetate, diflucortolone valerate, flumethasone pivalate, fluclorolone acetonide, fluocinolone acetonide, fluocionoide, fluocortin butyl, flucortolones, fluprednidene acetate,

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

flurandrenolone, halcinonide, hydrocortisone, hydrocortisone acetate, hydrocortisone butyrate, methylprednisolone acetate, nometasone furoate, triamcinolone acetonide, diclofenac, ibuprofen, acetylsalicylic acid, piroxicam, ketoprofen, felbinac, benzylamine, and combinations thereof.

5. (original) The formulation of claim 3 wherein the concentration of the anti-inflammatory agent is from about 0.01% to 10%.

6. (Previously Presented) The formulation of claim 1 wherein the active agent is a topical anesthetic.

7. (original) The formulation of claim 6 wherein the topical anesthetic is selected from the group consisting of lidocaine, prilocaine, bupivacaine, levo-bupivacaine, ropivacaine, mepivacaine, procaine, chlorprocaine, propoxycaine, hexylcaine, tetracaine, cyclomethycaine, benoxinate, butacaine, proparacaine, butamben, diperodon, phenacaine, falcaine, dyclonine, pramoxine, dimethisoquien, benzocaine, amethocaine, dibucaine, ketocaine, propanocaine, propipocaine, and combinations thereof.

8. (original) The formulation of claim 6 wherein the concentration of the anesthetic is from about 1% to about 10%.

9. (Previously Presented) The formulation of claim 1 wherein the active agent is an antibiotic or antifungal agent.

10. (previously presented) The formulation of claim 9 wherein the active agent is an antifungal agent is selected from the group consisting of clotrimazole, econazole, ketoconazole,

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

itraconazole, miconazole, oxiconazole, sulconazole, butenafine, naftifine, terbinafine, undecylinic acid, tolnaftate, nystatin, and sertaconazole nitrate.

11. (original) The formulation of claim 9 wherein the concentration of the antifungal or antibiotic agent is from about 0.3% to 5%.

12. (Currently Amended) A method of making a hydrofluoroalkane containing topical foam formulation free of volatile lower alcohols comprising

(a) making an oil in water emulsion with a ~~predominantly~~, more than 50%, aqueous phase, wherein the oil phase of the emulsion is a solid or semi-solid at room temperature

(b) either dissolving an active agent or agents selected from the group consisting of anti-inflammatory agents, topical anesthetics, topical antibiotics, anti-fungal agents, and combinations thereof in the aqueous or oil phase prior to emulsification or adding non-water soluble, non-oil soluble drug to the emulsion to form a dispersion in the emulsion, and

(c) adding a propellant consisting essentially of a hydrofluoroalkane or a mixture of hydrofluoroalkanes, without additional co-solvents or co-propellants, to the emulsion to produce an immediate foaming action on expulsion from a pressurized container.

13. (previously presented) A hydrofluoroalkane containing topical foam formulation free of volatile alcohols produced by the method of claim 12.